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10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,740	MACGREGOR, ALEXANDER	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-12,14-32,34,35 and 37-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,14-32,34,35 and 37-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks, all filed 5/08/07. New claims 43-46 are added. Claims 1, 3-8, 10-12, 14-32, 34, 35 and 37-46 are pending.

Response to Arguments

Any rejections that are not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/08/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter.

Applicant stated on 8/28/06 that the specification at pages 28-34 and Tables 1-7 provide support for claim 42. The Examples on pages 28-34 does not have ratio of hydrodynamic fluid imbibing polymer (CARBOPOL) to agent of interest from 1:1 to 9:1. The examples are calculated at 4 : 1, 3:1, 2.85:1 and 8.5:1. The specification as filed does not envision a ratio of hydrodynamic fluid-imbibing polymer to agent in a range of 1:1 to 9:1; the original specification envisions specific points as shown above and not a range. The original specification does not also envision a weight ratio of hydrodynamic fluid imbibing polymer to hydrostatic pressure modulating agent of from 35:1 to 167:1.

The above rejection may be overcome by removing the new matter from the claims.

Response to Arguments

4. Applicant's arguments filed 5/08/07 have been fully considered but they are not persuasive.

Applicant argues that the basis of the argument is contrary to the law regarding the written description requirement because applicant is not require to provide an example for every point within the claimed range; rather, applicant argues that the applicant must "recount his invention in such detail that his future claims can be determined to be encompassed within the creation," that "satisfaction of written description requirement is measured by the understanding of a person having ordinary skill in the art."

Response:

In the Amgen Inc. v. Hoechst Marion Roussel Inc. case, the issue was whether the specification described the use of exogenous human EPO DNA in human cells for claims directed to production of recombinant erythropoietin. In the present case, the issue is whether

the original disclosure envisions a ratio in the range of 1:1 to 9:1 for hydrodynamic fluid-imbibing polymer to agent or whether the original specification envisions a ratio in the range of about 35:1 to 167:1 for hydrodynamic fluid-imbibing polymer to hydrostatic pressure modulating agent. All points within the recited ranges claimed after the filling of the original specification need not all be exemplified, but that the original specification envision the ranges now claimed. In the instant case, these recited ranges in the claim added by amendment after the filling of the original specification are neither disclosed/described nor envisioned. Thus the Amgen Inc. v. Hoechst Marion Roussel Inc. does not appear to apply to the issue of new matter introduced into the claims by amendment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-5, 7, 8, 10, 12, 14, 21-23, 26-32, 34, 35, 38-41, 43, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dresdner, Jr. et al. (US 5,357,636).

Dresdner, Jr. discloses antiseptic composition comprising antiseptic agents such as povidone iodine, sodium hypochlorite, nonoxynol 9 and chlorhexidine gluconate, sodium dichloroisocyanurate, sodium perborate, to name a few (abstract; column 12, lines 50-67; column 27, lines 39-53; column 27, lines 40-50), surfactant (column 13, line 1), antibiotics (column 27, line 65 to column 28), bicarbonate or peroxide (column 30, line 51 to column 31 line 41),

viscosity modifying polymer/agent such as cross-linked polyvinylpyrrolidone and carbopol (column 35, line 56 to column 36 line 37). The cross-linked polyvinylpyrrolidone is the hydrostatic pressure-modulating agent of the claims 1 and 38-41. Carbopol is cross-linked with allylsucrose or allylpentaerythritol and is the cross-linked hydrodynamic fluid imbibing polymer of claims 1 and 38-41. Sodium perborate is the expansion source of claims 7, 38 and 39 and also meets claim 22 as the oxygen precursor source since the Dresdner does not describe borate as being wet. The hypochlorite meets the limitation of chlorine dioxide source and claim 23. The antiseptic composition of Dresdner is in a non-liquid form such as a dry solid (abstract; column 20, line 35; column 25, line 42), which meets the limitation that the hydrostatic delivery system is a solid in the claims 1 and 38-41. The release kinetics of zero order is independent of the concentration of the reactants that would be released and it is ultimately a property/characteristic of the dosage form so that it would be inherent that the non-liquid antiseptic composition of Dresdner would exhibit zero order kinetics for the release of the agent. Claims 3-5 recite the properties/characteristic of the delivery system. The carbonate of this reference is a carbonate source and thus meets the limitation of claims 7, 8 and 10; specifically ammonium carbonate is named (column 30, line 54 meeting claim 21. The solid compact or dry blend now recited in amended claims 1, 38 and 39 read on the powdered solid non-liquid composition of Dresdner. The antimicrobial of claim 26 broadly reads on the antiseptic of Dresdner. The non-liquid antiseptic composition optionally contains colorant (abstract) meeting the requirement for colorant, which is identified as an adjuvant in applicant's specification at paragraph [0097] in claims 27 and 28. The solid compact and matrix extrusion spheroid of claims 29 and 30 read on the powder of Dresdner and claims 29 and 30 are product by process

claims and how the matrix is produced does not accord patentable distinction to the product. Claims 31 and 32 are aloe product by process claims such that the composition of Dresden meets claims 31 and 32. The teaching of Dresdner, Jr. meets the limitations of the claims.

Response to Arguments

7. Applicant's arguments filed 5/8/07 have been fully considered but they are not persuasive.

Applicant states that Dresdner does not disclose or suggest the hydrostatic delivery system of "the presently claimed invention."

Response:

Dresdner discloses antiseptic composition in non-liquid form, such as dry solid, with the composition comprising CARBOPOL 934 (allylsucrose or allylpentaerythritol crosslinked acrylic polymer) or cross-linked polyvinylpyrrolidone or mixture thereof. The CARBOPOL and the crosslinked polyvinyl pyrrolidone and the antiseptic active agent and percarbonate or sodium perborate monohydrate or anhydrous sodium perborate make up the hydrostatic delivery system as claimed in claims 1, 38 and 39. The solid form of the claims reads on the powder of Dresdner. An agent being released in a zero order or near zero order controlled release is a property/characteristic of the dosage. The cross-linked polyvinylpyrrolidone is the hydrostatic pressure modulating agent of the claims 38 and 39. Carbopol is cross-linked with allylsucrose or allylpentaerythritol and is the cross-linked hydrodynamic fluid imbibing polymer of claims 1, 38 and 39. Sodium perborate is the expansion and oxygen precursor source of claims 7, 22, 38 and 39.

8. Claims 14, 17, 18, 20, 35, 37, 43, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Bai (US 5,840,329).

Bai discloses a dosage form in the tablet or capsule form that comprises dextran (column 3, line 52; column 7, line 24; claims 1, 4, 13 and 15), which is hydrodynamic fluid-imbibing polymer recited in claim 37 b) i), and claims 1 and 35; cross-linked polyvinylpyrrolidone (column 8, lines 16, 17; claims 1, 4, 13 and 15), which is hydrostatic pressure modulating agent of claim 37 b) ii) and claim 18; and active medicament (column 5, lines 6-17; column 6, line 7; column 10, lines 10-67; column 13, lines 1-11) meeting the active agent component of claim 37. The solid compact of claim 37 reads on the tablet of Bai. Claims 45and 46 recite the properties/characteristic of the composition of claim 37 and 43 and the composition of Bai and the properties/characteristic is inherent to the composition of Bai since a product/composition and its properties cannot be separated. Carbopol is also used in the blend of polymers (column 7, lines 38-43) meeting claim 14. Cross-linked carboxymethylcellulose and sodium starch glycolate (column 8, lines 15-20) meet the limitations of claims 20. Thus, Bai meets the limitations of the designated claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 5, 6, 15, 16, 19 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dresdner, Jr. et al. (US 5,357,636).

Dresdner discloses the claimed composition in claims 1, 3-5, 7, 8, 10, 12, 14, 21-23, 26-32, 34, 35, 38-41, 43, 44 and 46 as described above. Claims 6 and 15 recite the concentration of the polymer. The viscosity recited in claim 15 is a characteristic of the polymer at the recited concentration of the polymer at the specified temperature. Regarding claims 16 and 19, there is no demonstration that the recited particles provides unusual/unexpected results to the composition considering that Dresdner teaches powder composition, which are particles. Dresdner does not disclose the concentration of polymer in the composition. But, there is no demonstration that these amounts provides unexpected results. The artisan is however able to determine how much polymer to use in the composition that would provide the desired release of the antiseptic composition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the antiseptic solid composition Dresdner using amounts of polymer that is expected to provide the desired antiseptic effect.

11. Claims 1, 3-8, 10-12, 14-32, 34, 35, 40, 41, 43, 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838) in view of Conte et al. (US 5,780,057).

Rork discloses a tablet formulation (column 7, lines 21-42) comprising pharmaceutically active ingredients such as antimicrobials, local anesthetic, analgesics and anti-inflammatory agents (column 6, lines 18, 20, 24 and 18), excipients such as lactose, magnesium stearate, polyvinylpyrrolidone and dyes (column 8, lines 13-25), CARBOPOL polymer (column 8, lines

45-65) and carbonate (claims 10). See also column 13, line 20 to column 14, line 9). The combination of the CARBOPOL and the polyvinylpyrrolidone constitutes the hydrostatic couple of the instant application. The carbonate is the carbon dioxide precursor of the instant application. Rork teaches particulate formulation (column 8, lines 21-25) and the pharmaceutically active agents are present in amounts of from about 0.01% to about 75% of the core weight (column 8, lines 26-32). Rork does not disclose cross-linked polyvinylpyrrolidone. Ranitidine is one of the active agents in Rork (column 6, line 55). Conte discloses ranitidine composition that contains cross-linked polyvinylpyrrolidone (Example 4).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, Conte and Rork disclose ranitidine containing composition. Therefore, it would have been obvious to on of ordinary skill in the art at the time the invention was made to prepare the ranitidine composition of Rork. One having ordinary skill in the art would have been motivated to prepare a third composition comprising ranitidine, cross-linked polyvinylpyrrolidone, polyvinylpyrrolidone and carbopol with the expectation that this third composition when administered would function as ranitidine dosage form for inhibiting gastric ulcer secretion in ulcer patients. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

12. Applicant's arguments filed 05/08/07 have been fully considered but they are not persuasive.

Applicant states that Rork et al. or Conte et al. does not disclose or suggest the hydrostatic delivery system of "the presently claimed invention."

Response:

Both Rork and Conte teach tablet oral formulation. The "solid compact" now recited in the amended claims read of tablet and as such the combined teaching of the references meet the claims. The delivery device of Rork comprises a core that is made up of at least two layers (column 3, lines 33 and 34). In Conte, the second layer is hydrophilic and soluble and/or gellable and/or erodible and or swellable (column 7, lines 32 and 33).

Furthermore, applicant's arguments are directed to the individual references, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

B. Applicant states that improper hindsight reconstruction is adapted in the combination of Rork and Conte to arrive at the claimed invention.

Response:

13. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's disclosure had not been used as a guide to arriving at the obviousness rejection. Each of the two references discloses layered tablets for the oral delivery of at least ranitidine. Regarding the effect of cross-linked polyvinylpyrrolidone as a fast release polymer, it is noted that this polymer is the same polymer that is present in applicant's claimed delivery system. Since cross-linked polyvinylpyrrolidone is cross-linked polyvinylpyrrolidone, it stands to reason that the function or effect of the polymer would be the same in both the prior art and the claimed invention. Furthermore, Conte in column 3, lines 64-66 discloses that the dosage form exhibits high residence time in the stomach and or the first portion of the GI tract, which signifies delayed release. There is no disclosure of a burst or immediate release.

C. Applicant argues that the references taken alone or in combination does not provide zero order kinetics and that the swelling ability of the cross-linked polyvinylpyrrolidone would result is rapid hydration and concomitant expansion of the polymers so that the combination of Rork and Conte does not suggest all the elements of claims 1, 40 and 41.

Response:

An agent being released in a zero order or near zero order controlled release is a property/characteristic of the dosage. The cross-linked polyvinylpyrrolidone is the hydrostatic pressure modulating agent of the claims. The property or function of the cross-linked polyvinylpyrrolidone should not be different in the claimed delivery system and the delivery

system of the prior art. The combination of Conte and Rork discloses all the elements of claims 1m 40 and 41 as described above in the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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